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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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INTELLECTUAL PROPERTY GROUP
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EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,357

Applicant(s)

WHITE ET AL.

Examiner

Eileen O'Hara

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/12/01.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 40-70 are pending in the instant application.

Election/Restrictions

2. Applicant's election of the human species LIG-46 gene of SEQ ID NO: 13, encoding the polypeptide of SEQ ID NO: 14 in the paper filed August 19, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Oath/Declaration

3. Applicants should be aware that benefit of provisional applications are claimed under 35 USC § 119, and not under 35 USC § 120, and therefore, benefit has been accorded under 35 USC § 119.

Priority Statement

4. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent application 09/195,896. A statement reading "(now abandoned)" should be included after "09/195,896, filed November 19, 1998" following the title in the first sentence of the specification.

Claim Objections

5. Claims 40-43, 48-50, 55-58, 65 and 70 are objected to because of the following informalities.

5.1 In claims 46, 47, 68 and 69 and the specification the gene is written LIG46, but in claims 40-43, 48-50, 55-58, 65 and 70 the gene is written LIG-46. The claims should be amended to use consistent terminology.

5.2 In claim 55, the word "if" on the first line of section (g) should be removed to be grammatically correct.

5.3 In claim 70, the word "is" on the second line should be "in" to be grammatically correct.

5.4 Claim 70 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 70 fails to further limit the subject matter of claims 40, 48 and 55, because those claims inherently have a method step of measuring LIG46 expression in the absence of the test compound because a comparison is made between LIG46 expression in the presence and absence of the test compound.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 40-70 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 40-70 are directed to methods of for screening compounds to identify a candidate compound for altering food intake by a mammal, by treating cells expressing the protein of SEQ ID NO: 2 or 14 (mouse and human, respectively) which are identified as the products of the LIG46 gene, with a test compound, and measuring the effect of the test compound on the expression of the LIG46 gene. Claims 55-70 further comprise the steps of administering the test compound to a non-human mammal and monitoring the effect on eating behavior. However, the methods do not have any specific and substantial utility, or a well established utility, as determined according to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The specification teaches that the LIG46 proteins are similar to a number of galactosyltransferases, that it is homologous to *D. melanogaster* braniac protein, and that exposure of cells to leptin induces a number of genes, one of which is LIG46. On pages 97-98 of the specification it is taught that genetically obese mice (ob/ob, lacking the leptin gene), were injected with leptin, and that the LIG46 gene was induced in the hypothalamus of these mice compared to mice injected with just PBS. The instant application shows the results of two experiments, in which mice were treated with either sense or antisense LIG46, either alone or in conjunction with leptin, and the effect of treatment on food intake measured. In the experiment shown in Figure 6, ob/ob mice were treated (pages 98-99). The results show that are shown in Fig. 6. The leptin-induced decrease in food intake was far greater in the presence of LIG46 antisense oligonucleotide than LIG46 sense nucleotide or PBS control. The same experiment

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was performed with lean mice (pages 99-100), and the results shown in Fig. 11. The specification states on page 100:

“Thus, food intake can be decreased in lean mice by decreasing LIG46 protein expression. Moreover, this decrease in food intake is increased when leptin is administered, demonstrating that leptin can sensitize lean mice to the effects of a LIG46 antagonist.”

Therefore, the specification demonstrates that decreasing LIG46 expression results in a decrease of food intake. However, the specification also teaches that a compound that increases LIG46 expression (leptin), also results in a decrease of food intake. These results are inconsistent. From the results presented in the specification, there is no correlation between the expression levels of LIG46 and effect on eating behavior. Compounds that both increase (leptin) LIG46 expression and decrease (antisense LIG46) LIG46 expression both cause a decrease in food consumption. Therefore, it cannot be predicted that a compound that decreases LIG46 expression would be useful in reducing food intake, or that a compound that increases LIG46 expression would be useful for treating obesity. There are a number of factors that appear to control body weight, and are thought to play role in modulation of influencing factors such as appetite and satiety, fat storage, and energy output, and this regulation is quite complex (Halford J C; Blundell J E PROGRESS IN DRUG RESEARCH, (2000) 54 25-58, Halford J C, Curr Drug Targets, (2001 Dec) 2 (4) 353-70, Margetic S; Gazzola C; Pegg G G; Hill R A, INTERNATIONAL JOURNAL OF OBESITY AND RELATED METABOLIC DISORDERS, (2002 Nov) 26 (11) 1407-33 and Druce Maralyn; Bloom Stephen, CURRENT OPINION IN CLINICAL NUTRITION AND METABOLIC CARE, (2003 Jul) 6 (4) 361-7.

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The activity of the LIG46 protein is not known or disclosed, and because of the conflicting results, the data provided in the specification do not support the assertion that a compound that decreases expression of LIG46 can be used to treat obesity, or that a compound that increases LIG46 expression can be used for weight gain. Thus, the data do not support the assertion that any compound that modulates the expression of LIG46 can be used to modulate weight. Significant further research would have been required of the skilled artisan to determine the relationship between LIG46 expression and weight modulation, and thus the utility for the screening methods is not substantial.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 40-70 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 43, 51, 58 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43, 51, 58 and 61 are indefinite because they encompass the methods of claims 40, 48 and 55, respectively, in which LIG46 expression is measured in the presence of the test compound and leptin (or non-human mammal is exposed to the test compound and leptin), and it is not clear when the leptin is administered.

Pertinant Art

10. The art considered pertinent to the present application is Soppet et al., US Application Publication No. 20020110867, which discloses a polypeptide identified as Cardiac And Pancreatic Protein (CAPP) (see Fig. 1), which is 100 % identical to the polypeptide of SEQ ID NO: 14 of the present application. This reference does not teach or suggest what is being claimed, but is cited as the same protein as that in the instant claims.

Also pertinent to the present application is Zhou et al., Proc. Natl. Acad. Sci., Vol. 96, pp. 406-411, January 1999, and Egan et al., Glycoconjugate Journal, Vol. 17, No. 12, pp. 865-872, Dec. 2000. These references disclose proteins that are 99.2% and 99.5% identical to the protein of SEQ ID NO: 2 of the instant application, and teach that these proteins function as N-acetylglucosaminyltransferases.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.


Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



**LORRAINE SPECTOR
PRIMARY EXAMINER**